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09/428,203	10/27/1999	CHRISTOPHER O. OKUNJI	003/172/SAP	4366

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EXAMINER

FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
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1655

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/428,203

Applicant(s)

OKUNJI ET AL.

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35, 38 and 40 is/are pending in the application.
- 4a) Of the above claim(s) 2-10, 13-29 and 32-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1, 11, 12, 30, 31, 38 and 40 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgment is made of the receipt of the declaration filed under Rule 1.132 by Christopher O. Okunji, Ph. D on December 20, 2006.

Applicant's arguments, as well as the arguments set forth in the 1.132 Rule Declaration of Dr. Okunji, have been fully considered and found persuasive. Therefore, the rejection made under 35 U.S.C. 102(b) as being anticipated by the teachings of Ekpendu et al. (U), as forth in the previous Office action is vacated herein.

Response to Arguments

Election/Restrictions

Applicant's election with traverse of the following species: *Napoleonaea imperialis*, the solvent methanol and the seed portion of the plant, in the reply filed on April 12, 2007 are acknowledged. Further acknowledgment is made of Applicant's indication that the elected invention is readable on Claims 1, 11, 12, 30, 31, 38 and 40 are under examination.

The traversal is on the grounds that a search for plants exhibiting anti-leishmanial activity will invariably include a search for *N. imperialis*; that search for anti-leishmanial activity of *N. imperialis* and all portions of a plant; and; that a search for solvents will include others including those recited in the claims of the present invention. However, this is not found persuasive because the claim-designated members of the recited Markush group of Claim 1 are characterized by divergently different botanical extracts; and the search for one of the plant members does not require the search for any of the

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other plant members. For instance, a search for *N. imperialis* would not require a search of any of *Aframomum aulocacarpus*, *Aframomum daneilli*, *Dracaena arborea*, *Eupatorium odoratum* and *Glossocalyx brevipes*. This is also not found persuasive because the claim-designated members of the recited Markush group of Claim 12 are characterized by divergently different botanical parts of the plant; and, the search for one plant part, such as a root, would not require the search for another plant, such as a flower or petal or any other aerial plant part. This is also not found persuasive because the claim-designated members of the recited Markush group of Claim 30 are characterized by divergently different chemical constituents; and, a search for one solvent would not require a search for another solvent type. Moreover, additional search terms would be required for a thorough search of the claimed products, thus resulting in a larger more burdensome search for the examiner, especially since the claimed products comprise numerous permutations of numerous ingredients contained therein.

The requirement is still deemed proper and is therefore made FINAL.

The claims have been examined, insofar, as they read on the elected invention.

Claims 1, 11, 12, 30, 31, 38 and 40 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 30, 31, 38 and 40 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide prior support or antecedent basis for the language “a non-hydrolyzed extract” in Claims 11 and 30. The claims as set forth in the amendment filed on December 20, 2006 now recite a “a non-hydrolyzed extract”. However, the specification as originally filed provides does not preclude compositions that are not a “a non-hydrolyzed extract” *per se*.

Insertion of the above mentioned claim limitation has no support in the as-filed specification. The insertion of the limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genera which would show possession of the concepts for a composition comprising a non-hydrolyzed methanol extract from powdered seeds of *Napoleonaea imperialis* with regard to Claims 11 and 30. There is not sufficient support for the new aforementioned genera/genus to preclude compositions that are not a “a non-hydrolyzed extract”. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references

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cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim limitation is considered to be the insertion of new matter for the above reasons.

As the above-mentioned claim limitation could not be found in the present specification, the recitation of the claim limitations is deemed new matter; and, therefore it must be omitted from the claim language, unless Applicant can particularly point to the specification for literal support.

It is noted that because claims 31, 38 and 40 depend either directly or indirectly upon Claims 11 and 30, these claims necessarily contain all of the limitations of Claim 11 or Claim 30 and therefore also contain new matter and are properly rejected under this statute.

Legal Standard for Anticipation/Inherency Under - 35 USC § 102

To anticipate a claim under 35 U.S.C. 102(b), a single prior art reference must place the invention in the public's possession by disclosing each and every element of the claimed invention in a manner sufficient to enable one skilled in the art to practice the invention. *Scripps Clinic & Research Foundation v. Genetech, Inc.*, 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1001 (Fed. Cir. 1991); *In re Donahue*, 766 F.2d 531, 533, 266 U.S.P.Q. 619, 621 (Fed. Cir. 1985). To anticipate, the prior art must either expressly or inherently disclose each limitation of the claimed invention, *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365, 52 U.S.P.Q.2d 1303, 1303 (Fed. Cir. 1999) (citing to *In re Schreiber*, 128 F.3d 1473, 1477, 44 U.S.P.Q. 1429, 1431 (Fed. Cir.

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1997)); *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1347, 51 U.S.P.Q.2d 1943, 1946 (Fed. Cir. 1999). To inherently anticipate, the prior art, the prior art must necessarily function in accordance with, or include, the claimed limitations. *MEHL/Biophile*, 192 F.3d at 1365, 52 U.S.P.Q.2d at 1303. However, it is not required that those of ordinary skill in the art recognize the inherent characteristics or the functions of the prior art. *Id.* Specifically, discovery of the mechanism underlying a known process does not make it patentable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 11, 12, 30, 31, 38, as amended, remain, and, newly submitted Claim 40 is rejected under 35 U.S.C. 102(b) as being anticipated by Kapundu et al. (U). Applicant's arguments, as well as the arguments set forth in the 1.132 Rule Declaration of Dr. Okunji, have been fully considered. However, the rejection remains for the reason set forth in the previous Office action and for the reason set forth herein, slightly altered to address the amendment to the claims.

Applicant claims a biologically active extract comprising an extract from at least one plant selected from the group consisting of *Aframomum aulocacarpus*, *Aframomum daneilli*, *Dracaena arborea*, *Eupatorium odoratum*, *Glossocalyx brevipes* and *Napoleonaea imperialis*, wherein said extract is obtained using an organic solvent; and

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wherein said biologically active extract deters leishmanial activity. Applicant further claims a biologically active extract according to claim 1, wherein said extract is a non-hydrolyzed extract from powdered seeds of *Napoleonaea imperialis*; wherein said extract is from at least one of roots, stem bark, leaves, fruits or seeds from said plant; and, wherein said solvent is selected from a group consisting of hexane, chloroform, ethyl acetate and methanol and said extract is a non-hydrolyzed extract. Applicant further claims a biologically active extract according to claim 11, wherein said solvent is methanol; and, wherein said extract is saponin-enriched.

Applicant's main argument is drawn to the idea that the amendment to the claims overcome the anticipatory teachings of Kapundu because the amended claims now encompass subject matter drawn to limitations of leishmanial activity, seed extract, non-hydrolyzed methanol extracts and saponin extracts of *Napoleonaea imperialis*. Applicant further argues that the Examiner has misapplied the inherency doctrine. Thereby, Applicant concludes that the difference between what is taught in the prior art and what is instantly claimed is a methanol extract obtained from the powdered seeds of *Napoleonaea imperialis* comprising saponins and exhibiting activity against leishmania pathogens, and not hydrolyzed seed extracts of the claim-designated plant.

Given the foregoing, Applicant directs the Office to Applicants' 1.132 declaration: "The Examiner's attention is drawn to the Applicants' 132 declaration. Applicants distinguish Kapundu et al., by stating that the adopted hydrolysis of Kapundu et al., incurs 'significant concerns such as artifacts formation, not being able to obtain genuine aglycone, possibility of epimerization, transformation, etc.' See: page 7 of the 132

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declaration. This disclosure provides the necessary evidence as requested by the Examiner.” Applicant finally argues that the Kapundu’ reference directed to compound identification necessitating a hydrolysis step. In conclusion, Applicant argues that it is unclear as to how the examiner establishes an argument based on inherency: “Based on these unobvious distinctions between the applicants’ invention and the Kapundu, et al., reference, it is unclear how the examiner establishes an argument for inherency.

The Examiner has carefully considered Applicant’s position that the Kapundu’ reference fails to teach the instantly claimed invention and Applicant’s reasoning for the distinction between what is disclosed by Applicant and what is taught by the prior art reference. However, Applicant’s arguments are still not persuasive because Kapundu clearly teaches a methanol extract from powdered seeds of *Napoleonaea imperialis*, on page 615, Column 2, lines 11-12. Furthermore, Kapundu expressly teaches that the methanolic powdered seed extract of the claim-designated plant comprises saponin. For instance, on page 615, last line bridging page 616, line 1, Kapundu clearly teaches extracting the seeds of *Napoleonaea imperialis* with methanol and adding water to the methanolic extract to precipitate a saponin, which is separated by filtration. While Kapundu does teach identification of compounds contained therein the methanolic seed extract, thus necessitating a hydrolysis step of the extract, such disclosure by Kapundu does not negate the fact that Kapundu expressly teaches a methanolic extract obtained from powdered seeds of the claim-designated plant containing a saponin fraction therein. Therefore, while Kapundu does not expressly teach that the prior art methanolic plant extract has biological activity *per se*, biological activity is inherent to

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the extract taught by Kapundu because the source of the plant, the particular plant material from the source plant, and the solvent used in the making of the plant extract taught by Kapundu are one and the same as instantly claimed by Applicant. Therefore, antileishmanial activity extract of the methanolic extract of powdered seeds of *Napoleonaea imperialis* taught by Kapundu is inherent to the referenced extract, absent evidence to the contrary.

In the 1.132 Rule Declaration, Dr. Okunji argues that neither Ekpendu (see following rejection) nor Kapundu screened for biological or pharmacological activities of the constituents of claim-designated plant. In this regard, Dr. Okunji states, "Also both groups used similar methods in their chemical investigation of the major constituents of *N. imperialis* known as saponins. In all, both referenced papers the saponins were first hydrolyzed before isolation and chemical identification of the constituents." Unlike Applicant, Dr. Okunji argues that both Ekpendu and Kapundu worked on the hydrolyzed products of *N. imperialis*. For instance, Dr. Okunji explains that he explored the pharmacological activity of naturally occurring compounds rather than hydrolyzed products, which lead to the isolation of naturally occurring saponins contained in *N. imperialis*. The Office appreciates Dr. Okunji discussion of the distribution, isolation and identification of saponins in plants.

Dr. Okunji's arguments have been fully considered. However, they are not found persuasive because Kapundu expressly teaches a methanol extract of powdered seeds of *N. imperialis* comprising saponin. Given that the methanol extract comprised saponins that were not hydrolyzed, Kapundu teaches a non-hydrolyzed extract from

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powdered seeds of *N. imperialis*. And for the reasons clearly set forth above, the extract taught by Kapundu inherently deters leishmanial activity.

Applicant is invited to review the following:

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

The reference anticipates the claimed subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
May 28, 2007